

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

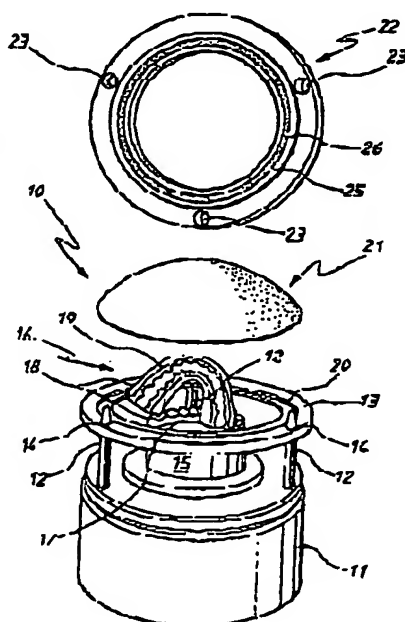
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- (21) International Application Number: PCT/AU00/01166 (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MY, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (22) International Filing Date: 26 September 2000 (26.09.2000) (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SI, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: PQ3121 27 September 1999 (27.09.1999) AU
- (71) Applicant (for all designated States except US): SIGNATURE MOUTHGUARDS PTY LIMITED (AU/AU); Level 1, 9 Carlotta Street, Annamoon, NSW 2064 (AU).
- (73) Inventor: and
- (75) Inventor/Applicant (for US only): RURNS, Peter (AU/AU); Level 1, 9 Carlotta Street, Annamoon, NSW 2064 (AU).
- Published:
— With international search report.
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: A MOUTHGUARD



(57) Abstract: A method to form a mouthguard, said method including the steps of providing a mould (14) to which a mouthguard shell (16) is applied. A sheet member (21) of resilient material is applied to the shell (16) and plastically deformed by applying a pressure differential across the sheet to thereby urge the shell (16) into contact with the mould (29) to plastically deform the shell (16) to form a mouthguard.

WO 01/22900 A1

Best Available Copy

A MOUTHGUARD

Technical Field

5 The present invention relates to mouthguards and more particularly, but not exclusively, to mouthguards used by sport participants.

Background of the Invention

10 Mouthguards have consisted of a number of types, including those constructed of thermoplastics material, which are heated (typically in hot water) and then applied to the user's mouth so that the mouthguard is moulded to fit the user's teeth and jaw. A more expensive type of mouthguard is as provided generally by dentists. The dentist "custom fitted" mouthguards are manufactured from an impression taken of the user's teeth and jaw. A sheet of plastics material is placed over the impression and plastically deformed
15 thereto by the use of heat and pressure.

The custom fitted mouthguards discussed above suffer from the disadvantage that there is not incorporated within the mouthguard features desirable for improving the level of protection for the user.

20 Object of the Invention

It is the object of the present invention to overcome or substantially ameliorate the above disadvantage.

Summary of the Invention

25 The present invention is a method to form a mouthguard to be worn by a user, the method includes the steps of:

providing a mould having a portion configured as a reproduction of a portion of a user's mouth;

30 locating on the mould a mouthguard shell to be plastically deformed by pressure to conform to said portion;

placing over the shell a deformable sheet so that the shell is located between the sheet and mould; and

applying a pressure differential across the sheet so that the sheet urges the shell against the mould to plastically deform the shell against said portion so that the mouthguard conforms to the configuration of the user's mouth.

Brief Description of the Drawings

A preferred form of the present invention will now be described by way of example with reference to the accompanying drawings wherein:

Figure 1 is a schematic perspective view of an apparatus to deform a mouthguard shell to the configuration of a mould;

Figure 2 is a schematic part section side elevation of the apparatus mould and mouthguard shell of Figure 1, in a first configuration;

Figure 3 is a schematic part section side elevation of the apparatus, mould and mouthguard shell as illustrated in Figure 2, in a further configuration; and

Figure 4 is a schematic section side elevation of an alternative sheet member employed in the apparatus of Figure 1.

Detailed Description of the Preferred Embodiment

Described in International Patent Application PCT/AU99/00458 are a number of mouthguard shells (budies) which can be plastically deformed so as to conform to the configuration of a user's mouth. The mouthguard shells disclosed in this international patent application may be employed in the apparatus 10 of Figures 1 to 3. However, in this respect it should be appreciated that the mouthguard shell described herein is formed from a suitable mouldable material and need not be a shell as described in the above PCT application.

In the accompanying drawings there is schematically depicted an apparatus 10 within which a mouthguard is formed. The apparatus 10 includes a base 11 from which there upwardly extends three posts 12. Inserted over the posts 12 is a sealing ring 13 which has apertures 14 through which the posts 12 pass.

The base 11 receives a mould 29 to deform the mouthguard shell 16. The mould 15 has a portion 17 produced from an impression taken from a patient's mouth, particularly the teeth and gums.

The mouthguard shell 16 is of a "C" configuration and is of a "U" transverse cross section. Typically, the mouthguard shell 16 would have the shape and configuration as illustrated in the above-mentioned PCT specification. The mouthguard shell 16 would

fit over the portion 17 so that the portion 17 is located between flanges 18 of the shell 16 and would in particular engage base 19 of the shell 16 to cause deformation thereof so that the mouthguard shell 16 conforms to the shape and configuration of the portion 17.

Typically, the shell 16 would be heated prior to being placed on the portion 17, so that when pressure is applied to the shell 16, the shell 16 plastically deforms. To apply pressure to the shell 16 there is provided a sheet member 21 formed of resilient material such as plastics or rubber material. In this embodiment the sheet member 21 is of a circular configuration so as to rest on the annular lip 20. To maintain the sheet member 21 in sealing contact with the ring 13 there is provided a clamp ring 22 which is of a similar configuration to the ring 13. The ring 22 has apertures 23 through which the posts 17 pass.

The ring 13 has an annular step 24 providing the lip 20. As best seen in Figures 2 and 3 the member 21 is engaged within the step 24.

The ring 23 has an annular projection 25 which is of a configuration to cooperate with the step 24 so that the member 21 has its annular periphery clamped between the rings 13 and 22. If so required the ring 22 can be provided with a sealing ring 26.

When the mouthguard shell 16 is to be deformed to form a mouthguard for the patient from which the impression has been taken, the shell 16 is heated and then placed on the portion 17. The apparatus 10 with the shell 16 is then placed in a machine which applies a pressure differential across the member 21. More particularly the machine includes a piston that engages with the upper surface 27 of the ring 22 and moves the rings 13 and 22 down into contact with the surface 28 of the base 11. The piston sealingly engages the surface 27 and applies a gas (preferably air) under pressure to the upper surface of the member 21. The member 21 then deforms about the shell 16 and forces the shell 16 onto the portion 17 to plastically deform the shell 16. The pressure above the member 21 is released and the rings 13 and 22 raised so that an operator may then remove the formed mouthguard.

In an alternative embodiment the rings 13 and 22 may be moved into contact with the surface 28 and then air withdrawn from below the member 21 so that air pressure above the member 21 exerts a force on the shell 16 to deform the shell 16.

In an alternative embodiment the member 21 may be preformed so as to be convex as illustrated in Figure 4. This would aid in minimising or eliminating forces generated by stretching the member 21 over the shell 16. In such an arrangement only the pressure differential across the member 21 would cause deformation of the shell 16.

In the above described preferred embodiments the member 21 may be rubber, latex, silicone or any other suitable synthetic elastomeric material. In the above embodiment the member 21 is of a domed configuration. However in an alternative embodiment the member 21 may be flat prior to elastic deformation and may be formed of elastic foil.

CLAIMS.

1. A method to form a mouthguard to be worn by a user, the method includes the steps of:

providing a mould having a portion configured as a reproduction of a portion of
5 a user's mouth;

locating on the mould a mouthguard shell to be plastically deformed by pressure to conform to said portion;

placing over the shell a deformable sheet so that the shell is located between the sheet and mould; and

10 applying a pressure differential across the sheet so that the sheet urges the shell against the mould to plastically deform the shell against said portion so that the mouthguard conforms to the configuration of the user's mouth.

2. The method of Claim 1 wherein the sheet has a shell side and a remote side, with the pressure on said remote side being increased to urge the shell against the
15 mould.

3. The method of Claim 1 wherein said sheet has a shell side and a remote side, with the pressure on said shell side being reduced to urge the shell against the mould.

4. The method of any one of Claims 1 to 4 wherein said sheet is formed of
20 natural of synthetic rubber, latex, silicone or elastic foil.

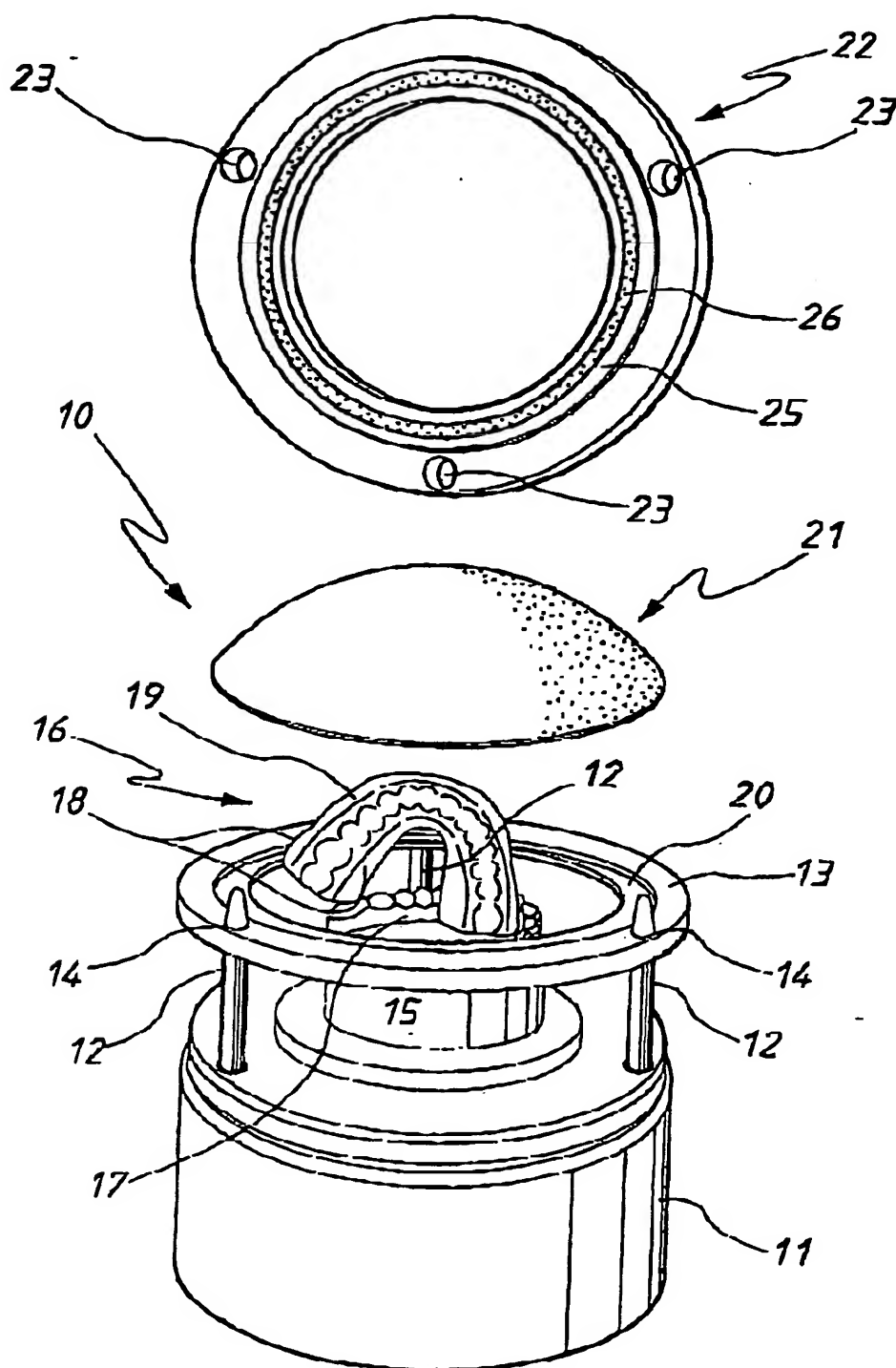
5. The method of any one of Claims 1 to 4 wherein said sheet is of a domed configuration prior to deformation.

6. The method of any one of Claims 1 to 4 wherein said sheet is flat prior to elastic deformation.

25 7. The method of any one of Claims 1 to 6 wherein said sheet is maintained at a spaced location relative to the shell prior to elastic deformation, and is subsequently moved towards said shell to cause initial elastic deformation of the sheet prior to applying said pressure differential.

8. A method to form a mouthguard to be worn by a user, substantially as
30 hereinbefore described with reference to the accompanying drawings.

9. A mouthguard formed by the method of any one of the previous claims.

FIG. 1

SUBSTITUTE SHEET (RULE 26)

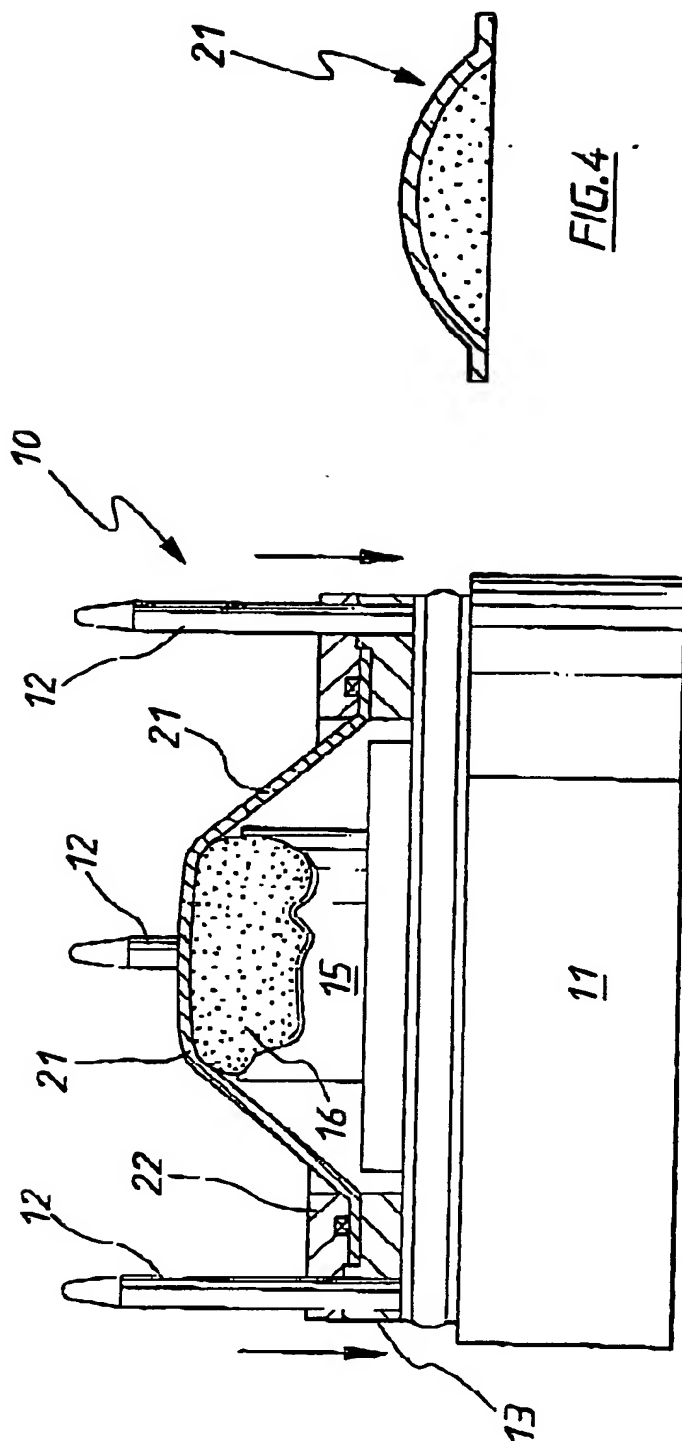


FIG. 4

INTERNATIONAL SEARCH REPORT

		International application No. PCT/AU00/01166
A. CLASSIFICATION OF SUBJECT MATTER		
Int. Cl. ⁷ A61C 5/14, A63 B 71/10		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) A61C 5/14, A63B 71/08, 71/10		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU: IPC AS ABOVE		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	AU 18016/95 C (Fastoute Pty Ltd) 11 September 1995 Page 5 line 37 - page 6 line 10	All
A	US 5692894A (Schwartz et al.) 2 December 1997 Column 4 lines 13-41	All
A	US 4848365A (Guarloti et al.) 18 July 1989 Column 3 lines 20-39	All
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input type="checkbox"/> See patent family annex		
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reasons (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"Z" document member of the same patent family</p>		
Date of the actual completion of the international search 5 December 2000		Date of mailing of the international search report 17 - DEC 2000
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6283 3929		Authorized officer JON MITCHELL Telephone No. (02) 6283 2113

The demand must be filed directly with the competent International Preliminary Examining Authority or, if more than one Authority is competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below:

IPEA/

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:
the undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty

For International Preliminary Examining Authority use only

Identification of IPRA		Date of receipt of DEMAND	
Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION		Applicant's or agent's file reference	
International application No PCT/AU00/01166	International filing date (day/month/year) 26 September 2000 (26/09/00)	477543C (Earliest) Priority date (day/month/year) 27 September 1999 (27/09/99)	
Title of invention A Mouthguard			
Box No. II APPLICANT(S)			
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) SIGNATURE MOUTHGUARDS PTY LIMITED Level 1 9 Carlotta Street Artarmon, New South Wales, 2064 AUSTRALIA		Telephone No.: Facsimile No.: Teleprinter No.:	
State (i.e. country) of nationality: AUSTRALIA		State (i.e. country) of residence: AUSTRALIA	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) BURNS, Peter Level 1, 9 Carlotta Street Artarmon, New South Wales, 2064 AUSTRALIA			
State (i.e. country) of nationality: AUSTRALIA		State (i.e. country) of residence: AUSTRALIA	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)			
State (i.e. country) of nationality:		State (i.e. country) of residence:	
<input type="checkbox"/> Further applicants are indicated on a continuation sheet. Form PCT/IPEA/401 (first sheet) (January 1994)			

See Notes to the demand form

[R:\LIB\T\20431.docx]

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is ☒ agent ☐ common representative
 and ☒ has been appointed earlier and represents the applicant(s) also for international preliminary examination.
☐ is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.
☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

Spruson & Ferguson
 GPO Box 3898
 Sydney, New South Wales 2001
 AUSTRALIA

Telephone No. :

(02) 9207 0777

Facsimile No. :

(02) 9232 8555

Teleprinter No. :

AA 23165

☐ Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. IV STATEMENT CONCERNING AMENDMENTS

The applicant wishes the International Preliminary Examining Authority*

- (i) ☒ to start the international preliminary examination on the basis of the international application as originally filed
 (ii) ☐ to take into account the amendments under Article 34 of
 ☐ the description (amendments attached).
 ☐ the claims (amendments attached).
 ☐ the drawings (amendments attached).
 (iii) ☐ to take into account any amendments of the claims under Article 19 filed with the International Bureau (a copy is attached).
 (iv) ☐ to disregard any amendments of the claims made under Article 19 and to consider them as reversed.
 (v) ☐ to postpone the start of the international preliminary examination until the expiration of 20 months from the priority date unless that Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)) (This check-box may be marked only where the time limit under Article 19 has not yet expired.)

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Box No. V ELECTION OF STATES

☒ The applicant hereby elects all eligible States (that is, all States which have been designated and which are bound by Chapter II of the PCT) except:

(If the applicant does not wish to elect certain eligible States, the name(s) or country code(s) of those States must be indicated above)

Box No. VI CHECK LIST

The demand is accompanied by the following documents for the purposes of international preliminary examination:

- | | | | |
|----|---|---|--------|
| 1. | amendments under Article 34 | : | sheets |
| | Description | : | |
| | Claims | : | sheets |
| | Drawings | : | sheets |
| 2. | letter accompanying amendments under Article 34 | : | sheets |
| 3. | copy of amendments under Article 19 | : | sheets |
| 4. | copy of statement under Article 19 | : | sheets |
| 5. | other (specify) | : | sheets |

For International Preliminary
Examining Authority use only

Received

not received




The demand is also accompanied by the item(s) marked below:

- | | | | |
|----|---|----|---|
| 1. | <input type="checkbox"/> separate signed power of attorney | 4. | <input checked="" type="checkbox"/> fee calculation sheet |
| 2. | <input type="checkbox"/> copy of general power of attorney | 5. | <input type="checkbox"/> other (specify): |
| 3. | <input type="checkbox"/> statement explaining lack of signature | | |

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Note: In each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).


 Ryan Clirmick
 Registered Patent Attorney
 SPRUSON & FERGUSON

For International Preliminary Examining Authority use only

1.	Date of actual receipt of DEMAND	
2.	Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):	
3.	<input type="checkbox"/> The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and Item 4 and 5, below, does not apply.	<input type="checkbox"/> The applicant has been informed accordingly
4.	<input type="checkbox"/> The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5	
5.	<input type="checkbox"/> Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.	

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Demand received from IPEA on:

Form PCT/IPEA/401 (last sheet) (January 1994)

See Notes to the demand form

PATENT COOPERATION TREATY
PCT
 INTERNATIONAL PRELIMINARY EXAMINATION REPORT
 (PCT Article 36 and Rule 70)

Applicant's or agent's file reference 477543c	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. PCT/AU00/01166	International Filing Date (day/month/year) 26 September 2000	Priority Date (day/month/year) 27 September 1999
International Patent Classification (IPC) or national classification and IPC Int. CL⁷ A61C 5/14, A63B 7/110		
Applicant SIGNATURE MOUTHGUARDS PTY LIMITED et al		

This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of **3** sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s)

3. This report contains indications relating to the following items:

- | | | |
|------|-------------------------------------|---|
| I | <input checked="" type="checkbox"/> | Basis of the report |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input type="checkbox"/> | Certain observations on the international application |

Date of submission of the demand 26 April 2001	Date of completion of the report 7 May 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer JON MILLS Telephone No. (02) 6283 2113

PCT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTICE INFORMING THE APPLICANT OF THE
COMMUNICATION OF THE INTERNATIONAL
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:

SPRUSON & FERGUSON
GPO Box 3898
Sydney, NSW 2001
AUSTRALIE

Date of mailing (day/month/year)

05 April 2001 (05.04.01)

Applicant's or agent's file reference

477543C

IMPORTANT NOTICE

International application No.

PCT/AU00/01166

International filing date (day/month/year)

26 September 2000 (26.09.00)

Priority date (day/month/year)

27 September 1999 (27.09.99)

Applicant

SIGNATURE MOUTHGUARDS PTY LIMITED et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
AU, KP, KR, US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE, AG, AL, AM, AP, AT, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EA, EE, EP, ES, FI, GB, GD, GE, GH, GM, GR, HU, ID, IL, IN, IS, JP, KE, KG, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MY, NZ, OA, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU.
The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 05 April 2001 (05.04.01) under No. WO 01/22900

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 18 months from the priority date.

It is the applicant's sole responsibility to monitor the 18-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Required Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO
34, chemin des Calanettes
1211 Geneva 20, Switzerland

Authorized officer

J. Zahra

Facsimile No. (41-22) 740.14.35

Telephone No. (41-22) 398.83.38

Form PCT/IB/308 (July 1990)

3928225

EXPRESS MAIL LABEL
NO.: EV 011021298 US

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference (if desired) (12 characters maximum)

477543C

Box No. I TITLE OF INVENTION
A MOUTHGUARD

Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)

SIGNATURE MOUTHGUARDS PTY LIMITED
Level 1
9 Carlotta Street
Artamon New South Wales 2064
AUSTRALIA

☐ This person is also inventor.

Telephone No.

9437 5600

Facsimile No.

9437 4531

Teleprinter No.

State (i.e. country) of nationality:

AUSTRALIA

State (i.e. country) of residence:

AUSTRALIA

This person is applicant for the purposes of:



all designated States



all designated States except the United States of America



the United States of America only



the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (i.e. country) of residence if no State of residence is indicated below.)

BURNS, Peter
Level 1
9 Carlotta Street
Artamon New South Wales 2064
AUSTRALIA

This person is:

☐ applicant only☒ applicant and inventor☐ inventor only (If this check-box is marked, do not fill in below.)

State (i.e. country) of nationality:

AUSTRALIA

State (i.e. country) of residence:

AUSTRALIA

This person is applicant for the purposes of:



all designated States



all designated States except the United States of America



the United States of America only



the States indicated in the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:

☒ agent☐ common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)

SPRISON & FERGUSON
GPO BOX 3898
Sydney
New South Wales 2001
AUSTRALIA

Telephone No.
(02) 9207 0777Facsimile No.
(02) 9232 8555Teleprinter No.
AA 23165

☐ Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Form PCT/RO/101 (first sheet) (January 1991; reprint January 1998)

See Notes to the request form

[R:LIBU]06560.doc:rah

EXPRESS MAIL LABEL
NO.: EV 011021298 US

The following designations are hereby made under Rule 4.9(a) (mark the applicable check boxes; at least one must be marked):

Regional Patent

- ☐ AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, MZ Mozambique, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☐ EA Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☐ EP European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☐ OA OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line):

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- | | |
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| <input type="checkbox"/> AE United Arab Emirates | <input type="checkbox"/> LC Saint Lucia |
| <input type="checkbox"/> AG Antigua and Barbuda | <input type="checkbox"/> LK Sri Lanka |
| <input type="checkbox"/> AL Albania | <input type="checkbox"/> LR Liberia |
| <input type="checkbox"/> AM Armenia | <input type="checkbox"/> LS Lesotho |
| <input type="checkbox"/> AT Austria | <input type="checkbox"/> LT Lithuania |
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| <input type="checkbox"/> GM Gambia | <input type="checkbox"/> TT Trinidad and Tobago |
| <input type="checkbox"/> HR Croatia | <input type="checkbox"/> TZ United Republic of Tanzania |
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| <input type="checkbox"/> ID Indonesia | <input type="checkbox"/> UG Uganda |
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| <input type="checkbox"/> IN India | <input type="checkbox"/> UZ Uzbekistan |
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| <input type="checkbox"/> JP Japan | <input type="checkbox"/> YU Yugoslavia |
| <input type="checkbox"/> KE Kenya | <input type="checkbox"/> ZA South Africa |
| <input type="checkbox"/> KG Kyrgyzstan | <input type="checkbox"/> ZW Zimbabwe |
| <input type="checkbox"/> KP Democratic People's Republic of Korea | |
| <input type="checkbox"/> KR Republic of Korea | |
| <input type="checkbox"/> KZ Kazakhstan | |

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet.

Precautionary Designation Statement. In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except the designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15 month time limit.)

Form PCT/RO/101 (second sheet) (July 2000)

See Notes to the request form

Box No. VI PRIORITY CLAIMFurther priority claims are indicated in the Supplemental Box ☐

The priority of the following earlier application(s) is hereby claimed:

Country (to which, or for which, the application was filed)	Filing Date (day/month/year)	Application No.	Office of filing (only for regional or international application)
item (1) Australia	27 Sep 1999	PQ3121	

Mark the following check-box if the certified copy of the earlier application is to be issued by the Office which for the purposes of the present international application is the receiving Office (a fee may be required):

☒ The receiving Office is hereby requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s):

(1)

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) (If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):

ISA/

Earlier search Fill in where a search (international, international-type or other) by the International Searching Authority has already been carried out or requested and the Authority is now requested to have the international search, to the extent possible, on the results of that earlier search. Identify such search or request either by reference to the relevant application (or the translation thereof) or by reference to the search request.

Country (or regional Office):

Date (day/month/year)

Number:

Box No. VIII CHECK LIST

This international application contains the following number of sheets:

- | | | |
|----------------|---|----------|
| 1. request | : | 3 sheets |
| 2. description | : | 4 sheets |
| 3. claims | : | 1 sheets |
| 4. abstract | : | 1 sheets |
| 5. drawings | : | 3 sheets |

Total : 12 sheets

This international application is accompanied by the item(s) marked below:

- | | |
|---|---|
| 1. <input type="checkbox"/> separate signed power of attorney | 5. <input checked="" type="checkbox"/> fee calculation sheet |
| 2. <input type="checkbox"/> copy of general power of attorney | 6. <input type="checkbox"/> separate indications concerning deposited microorganisms |
| 3. <input type="checkbox"/> statement explaining lack of signature | 7. <input type="checkbox"/> nucleotide and/or amino acid sequence listing (if relevant) |
| 4. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s): | 8. <input type="checkbox"/> other (specify): |

Figure No. of the drawings (if any) should accompany the abstract when it is published.

Box No. IX**SIGNATURE OF APPLICANT OR AGENT**

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

Greg Turner
 Greg Turner
 Registered Patent Attorney
 SPRUSON & FERGUSON

For receiving Office use only

1. Date of actual receipt of the purported international application:

3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application.

4. Date of timely receipt of the required corrections under PCT Article 11(2):

5. International Searching Authority specified by the applicant: ISA/

6. ☐ Transmittal of search copy delayed until search fee is paid

2. Drawings

☐ received☐ not received

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Date of receipt of the record copy by the International Bureau:

Form PCT/RO/101 (last sheet) (January 1994; reprint July 1996)

See Notes to the request form

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/01166

A. CLASSIFICATION OF SUBJECT MATTER					
Int. Cl. ⁷ : A61C 5/14, A63 B 71/10					
According to International Patent Classification (IPC) or to both national classification and IPC					
B. FIELDS SEARCHED					
Minimum documentation searched (classification system followed by classification symbols) A61C 5/14, A63B 71/08, 71/10					
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU: IPC AS ABOVE					
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI					
C. DOCUMENTS CONSIDERED TO BE RELEVANT					
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.			
A	AU 18016/95 C (Fastcote Pty Ltd) 11 September 1995 Page 5 line 37 - page 6 line 10	All			
A	US 5692894A (Schwartz et al.) 2 December 1997 Column 4 lines 13-41	All			
A	US 4848365A (Guarlotti et al.) 18 July 1989 Column 3 lines 20-39	All			
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input type="checkbox"/> See patent family annex					
<table style="width: 100%; border: none;"> <tr> <td style="width: 33%; vertical-align: top;"> * Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed </td> <td style="width: 33%; vertical-align: top;"> "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family </td> <td style="width: 33%;"></td> </tr> </table>			* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family	
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Date of the actual completion of the international search 5 December 2000		Date of mailing of the international search report 17 - DEC 2000			
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929		Authorized officer JON MILLS Telephone No : (02) 6283 2113			

514

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

REC'D 15 MAY 2001

WIPO

PCT

Applicant's or agent's file reference 477543c	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU00/01166	International Filing Date (<i>day/month/year</i>) 26 September 2000	Priority Date (<i>day/month/year</i>) 27 September 1999
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61C 5/14, A63B 71/10		
Applicant SIGNATURE MOUTHGUARDS PTY LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- | | | |
|------|-------------------------------------|---|
| I | <input checked="" type="checkbox"/> | Basis of the report |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input type="checkbox"/> | Certain observations on the international application |

Date of submission of the demand 26 April 2001	Date of completion of the report 7 May 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer JON MILLS Telephone No. (02) 6283 2113

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
 pages , as amended (together with any statement) under Article 19,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-9	YES
	Claims	NO
Inventive step (IS)	Claims 1-9	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-9	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

All the documents cited in the ISR were category A only. Therefore the claimed invention is not disclosed in any of these patent documents and hence all the claims are novel.

Further, the claimed invention is not obvious in the light of any of the cited documents nor disclosed in any obvious combination, nor would the claimed invention be obvious to a person skilled in the art in the light of common general knowledge by itself or in combination with any of these documents.

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